



**NTP**  
National Toxicology Program

# NTP Study Nominations

Dr. Scott Masten

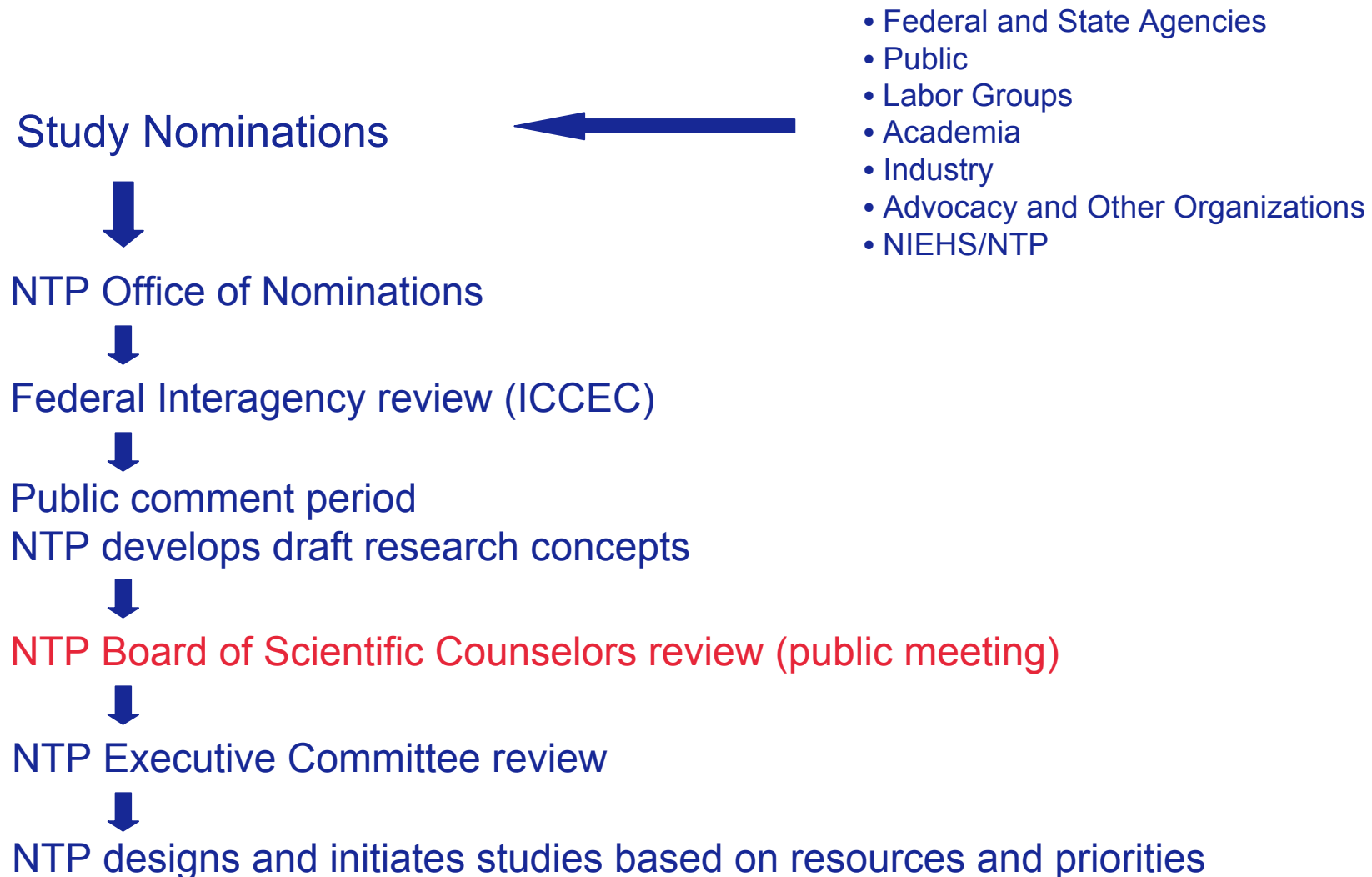
NTP Board of Scientific Counselors Meeting

December 6, 2007





# NTP Study Nomination Review Process





## New Study Nominations

- 10 new study nominations reviewed by the ICCEC, December 2006
- Preliminary study recommendations developed for each nomination
- Public comment period, April-May 2007
- Reviewed by the BSC, June 2007
  - Artificial butter flavoring and certain components
  - Asbestos, naturally occurring and atypical forms
  - Nanoscale silver
  - o-Phthalaldehyde
- Review by the BSC, December 2007
  - Aminopyridines
  - 2-Methoxy-4-nitroaniline
  - Diethyl phthalate
  - Nanoscale gold
  - 2',2''-Dithiobisbenzanilide
  - Pentaethylenehexamine



## Format for BSC Review

- NTP staff have prepared draft research concepts for 5 of the 6 nominations
  - Nomination background and rationale, significance, study approach, expected outcome
  - Proposed approach to address preliminary study recommendations for each nomination, not experimental study design
    - Outline key issues, data gaps, hypotheses, specific aims
- Presentation of research concepts by NTP project leaders
- Comments from Board and *ad hoc* reviewers
  - Response to charge questions
- Board discussion
- Public comments
- Board vote
  - Does nomination warrant study by the NTP?



## **Charge Questions for BSC Review of Study Nominations and Draft Research Concepts**

- Is a clear and valid rationale for the proposed research program articulated in the NTP research concept document?
- Does the proposed research program address an important area of biomedical research (e.g. children's health, genetic susceptibility, specific environmental disease) and/or advance the field of environmental health sciences?
- Is the proposed research program as outlined in the research concept document appropriate in scope given the public health importance of the issue or substance proposed for study? Are there other studies that should be considered as part of this research program?
- Does the proposed research program merit utilization of NTP resources, and if so, what priority (low, moderate, or high) should it be given?



## Today's Session

- Introduction to study nomination reviews
- Research concepts for new study nominations
  - Aminopyridines (Dr. June Dunnick)
  - 2-Methoxy-4-nitroaniline (Dr. Rick Irwin)
  - Nanoscale gold (Dr. Nigel Walker)
  - 2',2'''-Dithiobisbenzanilide (Dr. Mike Sanders)
    - Limited scope of proposed research program
- Study recommendation for Pentaethylenehexamine
  - No research concept prepared
- Research concepts for Diethyl phthalate and Phthalates Initiative (Dr. Paul Foster)
  - Latter is not a new nomination; follow-up to NTP peroxisome project, prior DEHP nomination/studies, CERHR critical data needs



**NTP**  
National Toxicology Program

## Questions and Comments